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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,421

12/15/2003

Lynetta Jean Freeman

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

07/30/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/736,421	<b>Applicant(s)</b> FREEMAN ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 32-47 is/are pending in the application.
- 4a) Of the above claim(s) 10, 25, 26, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-24, 27, 28 and 32-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 05/09/2008.

### ***Election/Restrictions***

Applicant's comments have been reviewed and it is agreed that claims 1-9, 1-24, 27, 28 and 31-47 read on the invention. It is noted however, that claim 31 has been cancelled.

The rejection under 35 USC 102(b) over Matsuura et al is withdrawn in view of applicant's remarks.

The following are new objections/rejections of the claims:

### ***Claim Objections***

Claims 32-47 are objected to because of the following informalities: The stil depend upon cancelled claim 31.. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon review of the specification, it was found that there is no explanation of "radio-opaque materials". A discussion of contrasting agents was found, therefore clarification is requested as to whether applicant is referring to these agents when referring to "radio-opaque materials". Aside from the biocompatible materials of the device, nothing was found with reference to the materials as set out in claim 6. As such, "radio-opaque materials" does not appear to be a limitation which applicant was in possession of at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-24, 27-28, 32-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, last line refers to "provide the biological product or function". This phrase is indefinite in that it is not particularly pointed out which product or function is being referenced. Further, if applicant is referring to the biological agent, metabolic or immunological function, the term as written now lacks antecedent basis. Clarification is requested.

Claim 21 recites the limitation "anti inflammatory" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

It appears that claim 21 should instead depend on claim 19. Correction is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11, 12, 19-21, 24, 27, 28, 32-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dionne et al (US Patent No. 5,798,113).

Dionne et al disclose an implantable drug delivery system which is capable of administering a biologically active agent or of providing a metabolic or immunological function; wherein the delivery device further comprises an external selectively permeable jacket comprising a biocompatible membrane which is a molecular weight cutoff permitting passage of active agent to and from the core (see Abstract). The device may have a core matrix formed by a hydrogel which may further contain cells (see col. 6, lines 52 – 60). Extracellular matrix as well as other nutrient components may be added at col. 7, lines 4-15. Efficient packing of cells for improved diffusion of critical solutes to the cells is described at col. 7, lines 16-54. The core matrix may further be considered a reservoir for nutrients as set out at col. 9, lines 48-67. Cells incorporated may be allogeneic or xenogeneic ( col. 10, lines 37-55). Size limitation by the molecular

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weight cutoff jacket is described at col. 11, lines 1-67; col. 12, lines 1-5. Addition of a hydrophobic substance to the vehicle is found at col. 12, lines 50-52. Anti inflammatory agents are specifically recited at col. 13, lines 43-55. Positioning the device in contact with the vascular system is found at col. 13, lines 57-63. Specific shaped forms of the device are listed at col. 18, lines 15-28; col. 23, lines 15-19, and include several which have a front and back surface. The maximum depth to surface distance at which cells should be present is set out at col. 18, lines 54-59. Maximum particle volume is set out at col. 19, lines 11-20. The number of cells can be 10,000, or as high as 500,000 as set out at col. 19, lines 35-50. Active agents are listed at col. 24, lines 40-67. A tether for the device is disclosed at col. 45, lines 18-27, and may be comprised of silicone. The instant claims are anticipated by Dionne et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615

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